

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 15, 1998 list were made in May, 1998

New Approvals

ANADA Number: 200-187

Pioneer Product: 135-773
Trade Name: Isoflurane, USP
Ingredients: Isoflurane
Sponsor: Marsam Pharmaceuticals, Inc.
Approval Date: 02/11/98
Status: Prescription only
Route: Inhalation
Species: Equine, Canine
Drug Form: Liquid
Concentration: 99.9%
Indications: For induction and maintenance of general anesthesia in horses and dogs

21CFR 529.1186 and 510.600

ANADA Number: 200-230

Pioneer Product: 048-854
Trade Name: Guaifenesin Injection
Ingredients: Guaifenesin
Sponsor: Phoenix Scientific, Inc.
Approval Date: 04/08/98
Status: Prescription only
Route: Intravenous
Species: Equine
Drug Form: Liquid (solution)
Concentration: 50 mg/mL
Indications: For intravenous use as a skeletal muscle relaxant in horses

21CFR 522.1086

NADA Number: 141-077

Trade Name: Adspec™ Sterile Solution
Ingredients: Spectinomycin sulfate
Sponsor: Pharmacia & Upjohn Co.
Approval Date: 01/28/98
Status: Prescription only
Route: Subcutaneous
Species: Bovine
Drug Form: Liquid (solution)
Concentration: 100 mg/mL
Indications: For the treatment of bovine respiratory disease(pneumonia) associated with *Pasteurella haemolytica*, *Pasteurella multocida*, and *Haemophilus somnus*
Tolerance: 21 CFR 556.600: an acceptable daily intake (ADI) of 0.025 micrograms/kg/day in tissue is established. A tolerance is established for parent spectinomycin (marker residue) of 0.25 ppm in muscle and 4 ppm in kidney (target tissue).
Withdrawal: 11 days
Exclusivity: 3 years

21CFR 522.2121 and 556.600

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 141-098

Trade Name: PropoFlo™
Ingredients: Propofol
Sponsor: Abbott Laboratories
Approval Date: 03/13/98
Status: Prescription only
Route: Intravenous
Species: Canine
Drug Form: Liquid (emulsion)
Concentration: 10 mg/mL
Indications: For induction of anesthesia, maintenance of general anesthesia up to 20 minutes, and induction of general anesthesia where maintenance is provided by inhalant anesthetics
Exclusivity: 3 years

21 CFR 522.2005

NADA Number: 141-101

Trade Name: Preempt™
Ingredients: Competitive exclusion culture (lyophilized bacterial cultures)
Sponsor: BioScience Division of Milk Specialties Co.
Approval Date: 03/13/98
Status: Over-the-counter
Route: Topical
Species: Avian (less than 1 day old chicks)
Drug Form: Powder
Concentration: 0.25 mL/chick of reconstituted culture
Indications: For the early establishment of intestinal microflora in chickens to reduce *Salmonella* colonization
Patent Number: 5,478,557 Expiration date: 12/13/2013
Exclusivity: 5 years

21 CFR 529.469 and 510.600

Supplemental Approvals

NADA Number: 038-878

Trade Name: Coban
Ingredients: Monensin
Sponsor: Elanco Animal Health, Division of Eli Lilly and Co.
Approval Date: 03/17/98
Status: Over-the-counter
Route: Oral
Species: Avian (chickens, turkeys, quail)
Drug Form: Type A Medicated Articles to make Type C medicated feeds
Concentration: 45 or 60 g/lb

This supplemental application provides for revised assay information used in checking the specifications of the monensin bulk drug substance used in Type A Medicated Articles.

21CFR 558.355

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 095-735

Trade Name: Rumensin
Ingredients: Monensin
Sponsor: Elanco Animal Health, Division of Eli Lilly and Co.
Approval Date: 03/17/98
Status: Over-the-counter
Route: Oral
Species: Bovine, Caprine
Drug Form: Type A Medicated Articles to make Type C medicated feeds
Concentration: 20, 30, 45, 60, 80 and 90.7 g/lb

This supplemental application provides for revised assay information used in checking the specifications of the monensin bulk drug substance used in Type A Medicated Articles.

21CFR 558.355

NADA Number 141-063

Trade Name: Nuflor® Injectable Solution
Ingredients: Florfenicol
Sponsor: Schering-Plough Animal Health Corp.
Approval Date: 04/02/98
Status: Prescription only
Route: Intramuscular
Species: Bovine
Drug Form: Liquid (solution)
Concentration: 300 mg/mL

This supplemental application provides for revised warning against use of the product in veal calves.

21CFR 522.955

NADA Number: 140-915

Trade Name: Interceptor® Flavor Tabs® for Cats
Ingredients: Milbemycin oxime
Sponsor: Novartis Animal Health US, Inc.
Approval Date: 04/13/98
Status: Prescription only
Route: Oral
Species: Feline
Drug Form: Tablet
Concentration: 5.75, 11.5, or 23.0 mg/tablet
Indications: For prevention of heartworm disease caused by *Dirofilaria immitis* and the removal of adult *Toxocara cati* (roundworm) and *Ancylostoma tubaeforme* (hookworm) infections in cats 6 weeks of age or greater and 1.5 pounds body weight or greater.
Patent Number: 4,547,520 Expiration Date: 06/14/2004
Exclusivity: 3 years

This supplemental application provides for expanding the indications to include separate dosage and labeling for use in cats. This product was previously approved for use in dogs.

21CFR 520.1445

Actions Taken by FDA Center for Veterinary Medicine

New Sponsor

Marsam Pharmaceuticals, Inc. Bldg. 31
24 Olney Avenue
Cherry Hill, NJ 08034
Drug labeler code: 000209

BioScience Division of Milk Specialties Co.
Illinois and Water Streets, PO Box 278
Dundee, IL 60118
Drug labeler code: 032761

Change of Sponsor

NADA Numbers: 102-020 & 111-349

From: Mallinckrodt Veterinary Operations, Inc.
To: Schering-Plough Animal Health Corp.
1095 Morris Ave
Union, NJ 07083
Drug labeler code 000061

Change of Sponsor Name

From: Protiva, a Unit of Monsanto
To: Monsanto Co.
800 North Lindbergh Blvd.
St. Louis, MO 63167
Drug labeler code: 059945

From: Hoffmann-La Roche, Inc.
To: Roche Vitamins, Inc.
45 Waterview Blvd.,
Parsippany, NJ 07054-1298
Drug labeler code: 063238

Withdrawals

NADA Number: 008-696

Trade Name: TM-5 Anitbiotic Feed Supplement
Sponsor: Pfizer, Inc.
Date: 05/12/1998

NADA Number: 011-034

Trade Name: Liquimast Solution For Mastitis
Sponsor: Pfizer, Inc.
Date: 05/12/1998

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: **013-470**

Trade Name: TM-10 Premix
Sponsor: Pfizer, Inc.
Date: 05/12/1998

Suitability Petition Action

Number: 98P-0190/CP1
Sponsor: Blue Ridge Pharmaceuticals, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug ivermectin/pyrantel pamoate which differs from the pioneer product, Heartgard-30[®] Plus, Merial Limited, NADA140-971, by the following characteristic: Ivermectin/pyrantel pamoate generic is a compressed chewable tablet and Heartgard-30[®] Plus is an “extruded” tablet.
Action: Filed on 3/26/98

Correction to a Suitability Petition Action

Number: 98P-0232/CP1
Sponsor: Virbac, Inc.
Last month’s Suitability Petition Action stated Pitman-Moore as the sponsor of Conofite[®] Spray 1.0%, NADA 095-184. It should have stated Conofite[®] Lotion 1.0% and Schering-Plough Animal Health Corporation.